IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **CASES LISTED IN PLAINTIFFS' MOTION AT EXHIBIT A (Doc. 8559-1)**	**WAVE 11**

DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF DEFENSE EXPERT LAWRENCE LIND, M.D. (WAVE 11)

Defendants Ethicon, Inc. and Johnson & Johnson file this Response to Plaintiffs' Motion to Limit the Opinions and Testimony of Defense Expert Lawrence Lind, M.D. (Mot., Doc. 8559; Mem. in Support, Doc. 8560).

I. OVERVIEW OF RESPONSE

Plaintiffs' motion is, in reality, a straw man fallacy. Plaintiffs do *not* challenge the overall qualifications of Dr. Lawrence Lind, a defense expert urogynecologist who was designated in five cases in Wave 11 specific to TVT, TVT-O, TVT Exact and TVT Abbrevo. Instead, based upon lines of questioning by Plaintiffs' counsel at Dr. Lind's August 7, 2019, deposition, Plaintiffs attempt to paint the picture that Dr. Lind has exceeded the boundaries of his fields of expertise. Review of Dr. Lind's actual testimony, however, reveals the argument to be hollow, in that Dr. Lind considers himself to have expertise in other disciplines *to the extent they are related to mesh slings*, which are exactly the issues he was designated to provide and which his expert report explains. Plaintiffs' argument that Dr. Lind is "alarmingly overconfident" in

other fields is a creation of Plaintiffs alone and is not supported by the record. Plaintiffs' challenge to Dr. Lind's qualifications fails.

The only other issue raised by Plaintiffs involves Dr. Lind's opinions regarding his patients' complication rates after mesh sling surgeries with a TVT product. Plaintiffs contend Dr. Lind employs an unreliable methodology, but again, the record shows otherwise. As Dr. Lind testified, primarily he relies upon the vast body of published medical literature to ascertain complication rates; and for his own patient population, he has more than a 90% follow up rate where he identifies patient complications. Plaintiffs' challenge to Dr. Lind's methodology also fails.

II. LAW & ANALYSIS

A. Dr. Lind has only been designated by Defendants as a general expert in urogynecology, and Plaintiffs do not challenge his qualifications in his field of expertise.

In the five cases subject to Plaintiffs' motion, Dr. Lind was designated by Defendants to offer general causation testimony in his specialty: **urogynecology**. *See, e.g.*, Exh. 1-5 (Defs.' Designation and Disclosure of General and Case Specific Expert Witnesses Pursuant to Pretrial Order in *Bain*, *Lopez*, *Ocasio*, *Oliver and Roman*). Given that designation, it is notable what Plaintiffs' motion does *not* challenge: Plaintiffs do not dispute Dr. Lind's expertise and ability to testify as to his specialty, **urogynecology**. In fact, Plaintiffs' Memorandum in Support demonstrates that Dr. Lind has extensive expertise in urogynecology; he is board-certified in obstetrics, gynecology, and female pelvic medicine and reconstructive surgery. Doc. 8560 at 1, 7 (acknowledging that Dr. Lind is "well-credentialed in his fields of obstetrics, gynecology, and female pelvic medicine and reconstructive surgery"); *see* also Lawrence Lind, M.D., Curriculum

Vitae (attached as Exh. D Pl. Mot.); Exh. 6: Lawrence Lind, M.D., Aug. 8, 2019, Dep. Tr.[1] 68:17-69:15, 72:24-76:19, 78:9-80:1, 86:6-87:5, 89:10-90:23, 170:14-22, 172:22-173:16, 226:19-227:2, 236:21-237:22, 237:23-238:4 (testimony regarding current medical practice, publications, lectures, and use of TVT products in hundreds of procedures over 25 years, as well as his reliance on coursework, literature, clinical experience, discussions with other experts, experience in research and development laboratories).[2]

What is more, Plaintiffs' *only* challenge to Dr. Lind's qualifications pertains to topics deemed "outside of his specialized field." *See* Doc. 8560 at 5. Dr. Lind's qualification to provide general opinions on urogynecology, as contained in his expert report, is thus not subject to any request for exclusion or limitation.

B. **Plaintiffs' only challenge to Dr. Lind's qualifications is a creation of counsel's questioning and is not supported by review of Dr. Lind's complete testimony.**

Although they are not challenging Dr. Lind's expertise in urogynecology, Plaintiffs' Memorandum contains a bullet point list of assertions aimed to challenge Dr. Lind's qualifications, which are cobbled together to argue that "Dr. Lind is Alarmingly Overconfident with Respect to His Fields of Expertise . . . ." *Id*. at 2-3, 5. Plaintiffs cite case law for an unremarkable proposition: that a witness must be qualified as an expert in his or her field, *see id.* at 6-7, and attempt to argue that Dr. Lind has strayed outside his field of expertise. More specifically, Plaintiffs claim that Dr. Lind considers himself an expert in chemical engineering, pathology, polymer chemistry, biomaterials, FDA regulations related to Instructions for Use (IFUs), IFUs and warning labels, and medical device design. *Id*. at 7.

---

[1] Dr. Lind's deposition was taken on August 7, 2019, and Plaintiffs' Motion attached the rough transcript. *See* Doc. 8560 at 2, n. 1. Defendants have attached and cite to the final transcript.

[2] Defendants also incorporate by reference their previously filed Response to Plaintiffs' Wave 6 motion to exclude Dr. Lind, *see* 2:12-md-2327, Doc. 4945 (Nov. 6, 2017), at 2-3, 4-6.

As a threshold issue, Plaintiffs fail to tie these accusations to any specific opinions contained in Dr. Lind's report, thus making analysis of Plaintiffs' argument difficult in that regard alone. But in any event, Plaintiffs' argument misconstrues Dr. Lind's actual testimony in three important ways.

First, neither Defendants' expert disclosure, nor Dr. Lind's expert report, purports to designate Dr. Lind as an expert beyond urogynecology. *See* Exh. 1-5, *supra; see also* Defense Expert General Report of Lawrence Lind, M.D., TVT, TVT-O, TVT Exact and TVT Abbrevo (June 24, 2019), attached to Pls. Mot. at Exh. C. *Second*, review of Dr. Lind's deposition transcript reveals that the claims of expertise in other fields was solely a creation of Plaintiffs' counsel's questioning during the deposition. And *third*, Plaintiffs offer only excerpts, whereas review of Dr. Lind's actual testimony reveals a key restriction: he considers himself an expert in various subjects *to the extent those topics relate to mesh slings*.

For instance, Plaintiffs claim that Dr. Lind considers himself an expert in chemical engineering, but that contention is imprecise at best. Dr. Lind was not designated by Defendants as a chemical engineering expert, and his report does not contain chemical engineering-specific *opinions*. Instead, the only reason the specter of chemical engineering arose was due to Plaintiffs' counsel's questioning—but even so, Dr. Lind's response demonstrates that he was explaining these components of his expertise *in the context of mesh slings*:

> Q. Do you consider yourself an expert on chemical engineering?
>
> A. **As it relates to slings, yes**.
>
> Q. And what is the basis? Why are you an expert in chemical engineering?
>
> A. Because the issues related to chemical engineering **as it pertains to tissue interaction with mesh and implants has been part of my career studying, implanting, taking care of patients, insuring their safety and observing the behavior. So that's 25 years of experience.**

Q. Do you have any education in chemical engineering?

A. I read quite a bit of literature **on the behavior of the mesh and how it interacts with tissue.** So my education is based on independent review of the literature. And I do not have a Ph.D.

Q. Well, I think we're talking about two different things. Are you talking about biomaterials right now versus chemical engineering? True?

A. Whether it's chemical engineering or biomaterials, **how they relate to the behavior of slings implanted in patients,** I consider myself an expert.

Q. You don't know anything about the chemical engineering of polypropylene mesh itself. True?

A. I would say that's false.

Q. Okay. Why is it false?

A. Because I've read articles about the process of it coming from resin, how it gets transformed from resin, and how it gets made into fibrils and how it gets made into the decision to how the fibrils get made and the width of the fibrils. So I've done reading on how they take it from powder and resin and transformed into materials and the reasons why they make decisions.

Q. So, is it your testimony that reading articles about how they make transvaginal -- excuse me. Polypropylene mesh is why you consider yourself a chemical engineering expert?

A. Reading articles, seeing the different outcomes of how the chemical engineering goes into making products different and seeing how it behaves in patients and seeing the outcomes for 25 years is my basis for stating I'm an expert on that topic **as it relates to mesh in sling behavior**.

Q. And you've seen all of that in your role as a physician. True?

A. Yes.

Lind Dep. Tr. 94:8-96:22 (emphasis added).

Plaintiffs' bullet-point snippets are similarly lacking for the other "fields" where Plaintiffs' counsel tried to portray Dr. Lind as having exceeded the boundaries of his expertise. *See id*. 97:11-23 (testimony regarding pathology expertise "[a]s it relates to the behavior of sling and mesh implanted in patients"), *id.* 99:15-101:6 (testimony regarding knowledge of literature

regarding pathologic specimens of mesh and sling materials, as well as review of pathology reports related to excised mesh in patients); *id*. 102:20-23, 103:4-6, 19-104:16 (testimony regarding polymer chemistry related to mesh and slings, participation in laboratory work that excises, tests and studies excised mesh under a microscope for inflammatory or histochemical changes, and 25 years' worth of experience implanting mesh, studying literature, and participating in educational, clinical and pathology education); *id*. 105:9-12, 14, 18-106:1 (testimony regarding publications and testing related to biomaterials and participation in cadaver laboratories); *id.* 106:10-15, 107:7-108:20, 112:5-9, 113:1-6 (testimony that Dr. Lind does not consider himself a comprehensive FDA expert, but he has expertise as it relates to adverse reactions and warnings in the IFU); *id.* 124:19-126:22, 132:8-20, (testimony regarding design of medical devices and experience over 25 years with testing of meshes, decreasing erosions, designing instruments, and proposals of designs).

As Dr. Lind's deposition testimony reveals, he is unquestionably an expert in urogynecology, and the breadth of his knowledge and experience—including his implantation of 2,500 to 3,000 mesh slings in his career—necessarily touches upon other fields as they relate to mesh slings. *See Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 190 (4th Cir. 2014) (district court abused its discretion in finding expert unqualified, and noting that a "witness may be qualified as an expert "by knowledge, skill, experience, training, or education," Fed.R.Evid. 702, and even though the expert "needed only one of those, *see Garrett v. Desa Indus., Inc.*, 705 F.2d 721, 724 (4th Cir.1983), the record demonstrated that he had them all.").

Moreover, this Court has determined that physician experts with extensive experience, like Dr. Lind, are qualified to opine on subjects such as design of a product, *see Tyree v. Boston Scientific Corp*., 54 F. Supp. 3d 501, 579-80, as amended (S.D. W. Va. Oct. 29, 2014) (finding a

urogynecologist qualified to opine on the properties of polypropylene and the safety of a specific sling device, despite his lack of credentials as a biomaterials expert, based on his extensive experience); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013), *on reconsideration in part* (June 14, 2013) (recognizing that a urogynecologist's "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders qualifies him to render opinions on [design] issues, notwithstanding his lack of expertise in the particular areas of product design or biomaterials"), and has also found physician experts qualified to opine on the risks of a device they are familiar with and whether those risks were expressed in the product's warning—which is what Dr. Lind's report provides here. Lind Rep. at 45-50; *see, e.g.*, *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL 2327, 2018 WL 3545341, at *3 (S.D. W. Va. July 23, 2018) ("Dr. Fiegen is not an expert in the development of warning labels. However, an urogynecologist—like Dr. Fiegen—is qualified to opine that the relevant IFU did not include risks observed by the expert in his or her clinical practice."); *Winebarger v. Bos. Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D. W. Va. Apr. 24, 2015) ("Dr. Shull will testify about the risks he perceives that the Uphold poses to patients, and he will opine that that the Uphold DFU did not convey these risks to physicians. A urogynecologist like Dr. Shull is qualified to make this comparison."); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 719 (S.D. W. Va. 2014) ("Dr. Blaivas need not be an expert on product warnings per se. Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT–O and whether those risks were adequately expressed on the TVT–O's IFU."); *see also In re Boston Scientific Corp. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2326, 2018 WL 2426223, at *4 (S.D. W. Va. May 30, 2018) (recognizing that expert doctors may properly opine on the knowledge of the

medical community in general). Plaintiffs' effort to suggest that Dr. Lind will opine beyond his expertise fails.[3]

C. **Dr. Lind's opinions regarding complication rates are based on a reliable methodology.**

Finally, Plaintiffs claim that Dr. Lind has not employed a reliable methodology to opine on complication rates because "he does not have a formal tracking method for patient outcomes."

---

[3] Further, Plaintiffs' citations to authority are also unhelpful to their position. For example, Plaintiffs' Memorandum at page 5 cites to *Mohney v. USA Hockey, Inc.*, 300 F. Supp.2d 556 (N.D. Ohio 2004), for the following principle: "[a] court should "exclude proffered expert testimony if the subject of the testimony lies outside the witness's area of expertise." 4 Weinstein's Fed. Evid. § 702.06[1], at 702–52 (2000). **In other words, a party cannot qualify as an expert generally by showing that the expert has specialized knowledge or training which would qualify him or her to opine on some other issue.**" (citing *Redman v. John D. Brush & Co.*, 111 F.3d 1174, 1179 (4th Cir.1997); *Barrett v. Atl. Richfield Co.*, 95 F.3d 375, 382b (5th Cir.1996)). The highlighted sentence, above, is a key distinction here: Dr. Lind is not proffered to testify "generally" nor does he possess knowledge that would qualify him on "some other issue." The contrary is true: Dr. Lind has expertise in the field of urogynecology and his years of education, training, and experience qualify him to testify as to mesh slings, as he testified. What is more, in *Mohney*, the district court actually found the experts at issue (mechanical engineers) to be qualified, so the decision is inapposite to Plaintiffs' argument for this additional reason. *See Mohney*, 300 F. Supp. 2d at 565, 568, *aff'd*, 138 F. App'x 804 (6th Cir. 2005).

Plaintiffs also cite to *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 2d 722, 730 (E.D. N.C. 2007), for the proposition that an expert witness may not merely "parrot" an opinion of others, *see* Pl. Mem. at 5, but there is no allegation here that Dr. Lind "parroted" any other expert witness. Further, the court did not find the computer science expert in *Bouygues* to be unqualified, but instead, determined that the court would hold a hearing to determine her precise areas of expertise. In *Redman v. John D. Brush & Co.*, 111 F. 3d 1174, 1179 (4th Cir. 1997), cited in Pl. Mem. at 5, a case involving burglary of safe, the court found that a metallurgical expert was qualified to opine on properties and characteristics of metal, although not industry standards specific to safes; this is not similar to Dr. Lind, who has 25 years of education, experience, and training with pelvic mesh devices.

Plaintiffs' citations also conflate the distinct issues of qualifications and reliability of the opinion. For instance, in *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995), cited in Pl. Mem. at 6, qualifications were not in issue: "[t]he question of admissibility only arises if it is first established that the individuals whose testimony is being proffered are experts in a particular scientific field; here, for example, the Supreme Court waxed eloquent on the impressive qualifications of [the experts]."

Doc. 8560 at 3, 8-9. Plaintiffs present only a threadbare portion of deposition excerpts, *see* Doc. 8560 at 3, but review of Dr. Lind's actual testimony reveals that he relies upon a reliable method to reach his conclusions.

First, although not acknowledged in Plaintiffs' Memorandum, Dr. Lind explained at his deposition that "[t]he main thrust of giving opinions on complication rates comes from the enormous data." Lind Dep. 210:18-23. Second, Dr. Lind explained his ability to identify complications sustained by his patients:

> It is our routine practice to have them come back at three months, six months, one year and two years, and the patients come back in high frequency. Do I know it's 99 percent? Do I know it's 90 percent? I don't. I know it's a high fraction. I know that the patients are --I know that the complication rates are low.
>
> We have a quarterly Pelvic Surgeon Society meeting in Manhattan, and we have an agreement with all the local experts where, maintaining patients' confidentiality, we will let each other know if problems and complications have come in that we're not aware about.
>
> So, I don't have an organized statistical study to tell you on my patients.
>
> I will state from my practice of seeing them regularly and insuring that they come back at those intervals, that I feel very confident that my efficacy and safety reflects that of the literature.

Lind Dep. 210:24-212:5.

Dr. Lind reiterated that he tracks complications through follow-up visits after implantation surgeries: he is able to see patients at one year and two year visits post-surgery, and he knows if they are having problems. *Id.* 212:16-213:8. He clarified in his deposition that he has a 90 to 95% return rate for his patients, *id.* 212:20-213:17, 215:18-23, 216:4-8, and he can identify the number of surgeries he has performed and the number of mesh erosions that have been revised; therefore, as Dr. Lind testified, "I can statistically quantify. . . . I can search for bladder injury and I can give it to you over an N, which would be the total number. I can

quantify prolonged catheterization due to voiding dysfunction." *Id*. 214:1-11. Contrary to Plaintiffs' argument, then, Dr. Lind does have a systematic method of following his patients, where more than 90% of his patients return for follow up so that he can assess their condition and identify any complications. *See id*. 215:18-217:23 (reiterating that he has a tracking system where more than 90% of patients come back for follow up visits, even though "most studies of two years don't do better than 90 percent," and he knows if those patients have problems).[4]

Given Dr. Lind's education, training, clinical experience, review of the medical literature, and his many decades of experience, he has employed a reliable methodology to arrive at his stated opinions regarding mesh slings. *See Eskridge*, 556 Fed. App'x at 190-91 (reversing district court's exclusion of expert: "We also can find no foundation for the district court's conclusion that [the expert's] opinion is not based on sufficient facts or data," where the expert's "involvement with hundreds of cases of accidents . . . and his decades of experience in the industry in general certainly provided him with a strong foundation for testifying regarding those facts.") (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 156, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999) ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.")).

[4] Plaintiffs' citation to *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 677 (S.D. W. Va. 2014), *see* Pl. Mem. at 8, is inapposite. There, the Court ruled that the challenged expert (Dr. Margolis) "explains that, when forming his opinion about the complication rates of a medical procedure, he "give[s] the benefit of the doubt to the patient." In other words, he "assume[s] the worst-case scenario" and errs on the side of opining as to a higher complication rate to better protect a patient. Dr. Margolis eventually admits that he has been evaluating the literature and forming his opinions for this case according to that principle as well. '[G]iv[ing] the benefit of the doubt to the patient'" is not a scientific basis for determining the complication rates associated with a mesh device." *See also Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-5762, 2014 WL 4851989, at *14 (S.D. W. Va. Sept. 29, 2014) (same). This bears no resemblance to Dr. Lind's testimony about his tracking of more than 90% of his patients for one-year and two-year follow up visits, coupled with his knowledge of the vast body of scientific literature.

Yet even if Plaintiffs' allegation—that Dr. Lind lacks a reliable "tracking" method—were true, Plaintiffs' argument still fails, because Dr. Lind did not only rely on what Plaintiffs characterize as anecdotal evidence: Dr. Lind further testified that the "preponderance of [his] opinion is based on the 4,000 articles on midurethral slings that are published." *Id.* 215:5-7; *see also id.* at 210:18-23 (testimony that the primary source of Dr. Lind's opinions on complication rates "comes from the enormous data."). Because Dr. Lind's testimony is based on a reliable methodology, Plaintiffs' argument is without merit.

III. CONCLUSION

Dr. Lind has more than sufficient qualifications to opine on his field of expertise, urogynecology, and issues related to pelvic mesh that impact his knowledge and experience. His methodology for assessing his patients' complication rates is reliable in itself, and is supported by the published medical literature. Plaintiffs' motion to limit Dr. Lind's testimony should be denied.

Respectfully submitted,

/s/ *William M. Gage*
William M. Gage (MS Bar No. 8691)
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4561
william.gage@butlersnow.com

/s/ *Susan M. Robinson*
Susan M. Robinson (W. Va. Bar No. 5169)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 24338
(304) 414-1800
srobinson@tcspllc.com

Counsel for Defendants Ethicon, Inc.,
and Johnson & Johnson

CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
William M. Gage